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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,194	04/23/2001	Timothy P. Croughan	98A9-USCROUG	2938

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PATENT DEPARTMENT
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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,194

Applicant(s)

CROUGHAN, TIMOTHY P.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-5,7-9,11,13-15,31,38,54,61,129-132,134-136,138,140-146,148-150,152,154-160,162-164,166 and 168-185.

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114.

Applicant's submission filed on 4 June 2004 has been entered.

2. A copy of the signed IDS filed 30 June 2001 is attached as requested by Applicant (page 30 of the Response). The IDS filed 4 June 2004 has been considered and a signed copy is attached hereto.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2003. Applicant's

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arguments filed 4 June 2004 have been fully considered but they are not persuasive.

Applicant argues that the herbicide resistance mechanism of PTA-904 is fully and accurately described in the specification (page 3, 2nd paragraph of the Remarks). This argument is not found to be persuasive because Applicant only describes what PTA-904 does, not what it is. More specifically, Applicant does not describe the structure of PTA-904 with such clarity as to demonstrate that Applicant was in possession of the invention as broadly claimed, *i.e.* derived progeny or a plant that has the herbicide resistance characteristics of PTA-904. Such a demonstration would require a description of the AHAS genomic structure such that the claimed invention would be distinguished from any other rice plant resistant to a sulfonylurea and/or an imidazolinone herbicide compound. Applicant argues that in the Inventor's December 18, 2002 Affidavit, which was filed in the Office on January 2, 2003, the assay that was described in the specification fully confirmed that the resistance mechanism was as predicted in the specification, namely, the herbicide resistance characteristics of PTA-904 are attributable to a mutant acetohydroxyacid synthase (AHAS), a mutant enzyme that displays direct resistance to imidazolinone herbicides (page 4, 3rd paragraph of the Remarks). Applicant further argues that written description may be provided in a prophetic example and that while the PTA-904 rice line was described in working examples, the AHAS herbicide resistance assay was described prophetically. To the extent that the prophetic example of the assay might be germane to the written description requirement, the prophetic example

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has been fully confirmed by subsequent experimental data as reported in Croughan's December 18, 2002 affidavit. This argument is not found to be persuasive because the evidence in the December 2002 Declaration only confirms that an AHAS mutant enzyme exists in PTA-904, not what structural feature of said enzyme contributes to the function of said mutant enzyme in the PTA-904 rice plant. The issue is not whether Applicant has adequately described the PTA-904 rice plant, but that Applicant has not described those special technical features of the PTA-904 rice plant that would adequately describe subsequent progeny thereof. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46).

Applicant argues that the present specification gives a clear, unambiguous description of what is considered a "derivative" of a herbicide-resistant plant (page 5 of the Remarks). Applicant further argues that if a definition provided in a specification is clear, then it logically follows that the same definition must set forth a written description of the term being defined (page 6, 1st paragraph of the Remarks). This argument is not found to be persuasive because the issue of the metes and bounds of the limitation "derivative" has been settled in the course of the prosecution of the instant application. The Examiner has already conceded that Applicant has adequately taught the metes and bounds of "derivative". But

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contrary to Applicant's assertion, just because the metes and bounds of a limitation are clear, this is not a presumption that Applicant has adequately described what is claimed.

Applicant argues that there simply is no requirement that the inventor describe every way in which the presence of his invention might be masked by the addition of other factors, and to distinguish whether the invention is present in such a cryptic situation (page 6, 5th paragraph of the Remarks). This argument is not found to be persuasive because the name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." (Federal Register Vol. 66, No. 4, page 1100, Comment 2, 5 January 2001) See also, *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. In the instant case, while Applicant describes that the PTA-904 rice plant has a mutant AHAS enzyme that confers herbicide resistance, Applicant does not describe any structural features of such mutant AHAS enzyme that would distinguish progeny of the PTA-904 rice plant from others.

Applicant argues that one of skill in the art could readily tell whether a hybrid between PTA-904 and a different source of herbicide resistance had been made, that herbicide resistance profiles for different mutants typically differ, and that by observing a hybrid's profile of resistance to various AHAS-acting

herbicides, one could generally tell whether different sources of resistance were present. Applicant further argues that using known techniques of genetics a person of ordinary skill in the art could readily determine whether different sources of resistance were present in a given plant, without undue experimentation (page 7, 2nd paragraph of the Remarks). These arguments are not found to be persuasive for the reasons given supra as directed to progeny plants. In addition, it is not the burden of another to adequately describe Applicant's invention, even if techniques of discovery are readily available it is Applicant's burden to adequately describe the invention.

Applicant's response on pages 7-9 under section (C) has been considered by the Examiner but is considered an improper response to the instant rejection. It is Applicant's opinion that "the PTO should not examine patent claims in a way that could provide a road map to encourage infringers to adopt the core of a claimed invention - that is, not to design around the claimed invention, but to adopt its very core - and yet avoid liability for infringement" (page 7, 3rd paragraph of the Remarks). Applicant appears to have misconstrued the Examiner's opinion in the previous Office action. The Examiner in no way intended to imply how one could avoid infringement of a patent arising from the instant application. The Examiner's sole intent was to evaluate patentability of the claimed invention. Such an argument is not deemed constructive to furthering the prosecution of the instant application.

In reference to the Examiner's assertion in the previous Office action that "Applicant does not describe how the genetic background of PTA-904 influences

these herbicide resistance characteristics", Applicant argues that data obtained since the application was filed confirm that the mutant AHAS from PTA-904 in fact behaves very similarly when incorporated into different genetic backgrounds, and that as shown in the enclosed new Declaration from inventor Dr. Timothy Croughan, the PTA-904 line has now been crossed with numerous other varieties as part of a breeding program and that the herbicide resistance phenotype has been essentially constant in the offspring of all these crosses, including varieties of both subspecies, *indica* and *japonica* (page 9, 2nd-4th paragraphs of the Remarks). This argument is not found to be persuasive because the instant rejection is not directed to predictability of producing herbicide resistant progeny plants.

Applicant argues that claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the "derivative" limitation, a further limitation directed to rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904 are adequately described (page 10 of the Remarks). This argument is not found to be persuasive for the reasons given supra as directed to progeny of the PTA-904 rice plant. The Examiner views that the PTA-904 rice plant has been adequately described in view of the deposit of biological material, as well as methods of using the PTA-904 rice plant. The issue of written description lies in the description of "derivative" plants or a plant having the herbicide resistance characteristics of the PTA-904 rice plant as broadly claimed.

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5. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the herbicide resistant rice plant 'PWC16' (deposited as ATCC Accession Number PTO-904) and methods of using same, does not reasonably provide enablement for any "derivative" or progeny of said deposited rice plant, any rice plant having the herbicide resistance characteristics of the plant 'PWC16' (deposited as ATCC Accession Number PTO-904) or methods of using such "derivative" or progeny rice plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2003. Applicant's arguments filed 4 June 2004 have been fully considered but they are not persuasive.

Applicant states that it appears that the only basis for the enablement rejection was essentially the same as the basis for the written description rejection (page 11 of the Remarks). For the purposes of clarity the Examiner will restate the basis of the instant rejection. The specification states that "Unless otherwise clearly indicated by context, a "derivative" of a herbicide-resistant plant includes both the progeny of that herbicide-resistant plant as the term "progeny" is defined above; and also any mutant, recombinant, or genetically-engineered derivative of that plant, whether of the same species or of a different species; where, in either case, the herbicide-resistance characteristics of the original

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herbicide-resistant plant have been transferred to the derivative plant" (paragraph spanning pages 31-32 of the specification). Hence, in the instant case Applicant has failed to adequately teach one of skill in the art how to make and use the invention as broadly claimed. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The issue also remains that Applicant has not taught how to distinguish the AHAS mutation of the PTA-904 rice plant from other rice plants comprising an AHAS mutation, hence Applicant invites experimentation in the instant case. In addition, the claims are not fully enabled because the claimed rice plant at claim 1 can be read to encompass a rice plant that is a "derivative" of ATCC accession number PTA-904, but the "herbicide resistance characteristics of the plant with ATCC accession number PTA-904" can be introduced from another rice plant. Since Applicant only teaches one of skill in the art that the "herbicide resistance characteristics" of the deposited plant appears to be an AHAS mutation, one of skill in the art would have required undue trial and error experimentation to duplicate the "herbicide resistance characteristics" in another rice plant and produce the claimed "derivative" rice plant (this is a reiteration from the Office action mailed 10 March 2003, page 9).

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Applicant argues that claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the "derivative" limitation, a further limitation directed to rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904 are adequately enabled (page 12, 1st paragraph of the Remarks). This argument is not found to be persuasive for the reason given *supra*.

Claim Rejections - 35 USC § 102/103

6. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275). This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2003. Applicant's arguments filed 4 June 2004 have been fully considered but they are not persuasive.

Applicant argues that the Terakawa paper on its face is clearly distinguishable from the claimed inventions (page 12, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons of record.

Applicant states that attempts are being made to acquire the seed mentioned in the Terakawa reference, but that it might be the case that this seed is no longer available, and that if seed were no longer available, then Terakawa would not be an enabling disclosure with respect to the specific rice lines in

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question (page 13, 2nd paragraph of the Remarks). This statement appears to be a misinterpretation of the rejection, which is directed to a rice plant that is a derivative of the PTA-904 rice line, not to the specific PTA-904 rice line itself.

Double Patenting

7. Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166 and 168-185 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 64, 66, 68 and 70 of copending Application No. 09/934,973. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2003. Applicant's arguments filed 4 June 2004 have been fully considered but they are not persuasive.

The Examiner has considered applicant's arguments as directed to the instant provisional rejection on pages 13-20 of the Remarks. The Applicant states that it is difficult for the Applicant to prepare a meaningful reply where the Applicant has previously given a specific traversal of the provisional rejection and the Office has offered no substantial response (page 14, 1st paragraph of the Remarks). For clarity purposes, the Examiner gives the following reason for the instant rejection. The instant claims are directed to a genus of "derived" progeny of the PTA-904 rice plant or to a plant that is a "derivative" and has the herbicide resistance characteristics of the PTA-904 rice plant, and is resistant to one or more specific sulfonylurea and/or imidazolinone herbicides (see claim 1 of the instant application). Claims 62 of the copending application is directed to a

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herbicide-resistant rice plant wherein the growth of said herbicide-resistant plants resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, just not having the same herbicide resistance characteristics of the plant with ATCC accession number 97523. As has been previously stated, a plant that is a "derivative" and has the herbicide resistance characteristics of the PTA-904 rice plant can encompass a broad genus of rice plants that do not necessarily have to carry the mutant AHAS encoding gene of PTA-904, hence the genus of rice plants encompassed by the instant claims are rendered obvious by the genus of rice plants of the copending application.

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Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.


DAVID H. KRUSE, PH.D.
PATENT EXAMINER
AU 1638

David H. Kruse, Ph.D.
5 August 2004

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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